

REMARKS/ARGUMENTS

The rejections presented in the Office Action dated February 1, 2011 (hereinafter “Office Action”), have been considered. Claims 1, 4, 6, 13-15, 18, 20, 21, 29, 30, 33, 36, 39-41, 48-50, 53, 55, 58, 60, 63 and 64 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1, 13-15, 18, 20, 33, 36, 39, 48-50, 53, 55, 60 and 63-64 are rejected based on 35 U.S.C. § 103(a) over U.S. Publication No. 2004/0220624 by Ritscher *et al.* (hereinafter “Ritscher”) in view of U.S. Patent No. 7,031,773 to Levine *et al.* (hereinafter “Levine”). Claims 4, 6, 21, 29-30, 40-41 and 58 are rejected based on 35 U.S.C. § 103(a) over Ritscher in view of Levine.

In the Office Action, it is alleged that Ritscher discloses the claimed invention, “but fails to disclose that it uses an impedance threshold developed for the particular patient of the exact method in which it determines if there is a lead related condition” (page 3, section 5). The Office Action acknowledges that Ritscher does not disclose disabling atrial ATP therapy in response to an atrial lead impedance measurement deviating from an impedance threshold developed for a particular patient by a predetermined factor indicating atrial lead dislodgement. Levine is relied on for purportedly disclosing measuring an impedance of an atrial lead and disabling atrial ATP therapy delivery in response to a measured impedance deviating from an impedance threshold by a predetermined factor. This reliance on Levine, however, is misplaced.

Levine discloses an impedance measuring circuit 112 that is used during an autocapture procedure. Levine teaches that its impedance measuring circuit 112 is “enabled and caused to measure the lead impedance of the bipolar pacing electrode configuration during the backup pulse” of an autocapture procedure if “there is a failure to detect an evoked response” (column 12, lines 4-14).

Levine does not disclose measuring lead impedance in connection with ATP therapy, as is contended in the Office Action. Levine teaches that only cardiac electrical signals (*e.g.*, P-

waves, R-waves, and other depolarization signals) from which timing intervals can be measured are used “in order to determine the type of remedial therapy that is needed,” such as “anti-tachycardiac pacing,” also referred to as ATP.

Levine is incorrectly characterized in the Office Action as “disabling atrial ATP therapy delivery in response to a measured impedance deviating from an impedance threshold by a predetermined factor” (page 3, section 6). The Office Action makes reference to column 11, lines 11-19 of Levine as purportedly teaching this feature. A review of this portion of Levine reveals that ATP is not mentioned nor disabling of atrial ATP therapy.

The suggestion on page 3, section 6 of the Office Action that “the step of switching the electrode configuration to an electrode configuration other than the current electrode configuration represents disabling atrial ATP therapy delivery to the electrode configuration previously receiving the therapy” is untenable. First, this relied-on portion of Levine describes switching the pacing electrode configuration for backup pulse delivery during an autocapture procedure. ATP therapy delivery is not mentioned whatsoever. Second, this relied-on portion of Levine describes switching the pacing electrode configuration for backup pulse delivery from a potentially defective electrode configuration to another electrode configuration to enable backup pulse delivery—not to disable backup pulse delivery.

In section 7 starting on page 4 of the Office Action, numerous references are made to Figure 3 of Levine and certain claims of Levine that purportedly disclose various processes involving ATP therapy delivery or processes occurring prior to or after an atrial arrhythmic episode is declared. Respectfully, Applicant can find no discussion or mention of ATP therapy delivery or processes involving ATP in the cited portions of Levine.

The Office Action fails to establish correspondence between Applicant’s features recited in independent claims 1, 20, and 36, and the teachings of Ritscher and Levine. Concerning claim 20, for example, the asserted combination has not been shown to teach or suggest numerous claimed features, including:

disabling atrial ATP therapy for delivery in response to any of the impedance, capture threshold, and sense amplitude measurements deviating from the impedance, capture threshold, and sense amplitude limits by predetermined

impedance, capture threshold, and sense amplitude factors, respectively *when the atrial arrhythmia monitoring does not detect atrial arrhythmia during the measuring*; and

disabling atrial ATP therapy for delivery in response to only impedance measurements deviating from the impedance limit by the predetermined impedance factor and disregarding deviations from the capture threshold and the sense amplitude limit for the purpose of disabling atrial ATP therapy when the atrial arrhythmia monitoring detects atrial arrhythmia during the measuring. [emphasis added]

Concerning section 11, starting on page 7 of the Office Action, it is contended that detecting an ambiguity in the impedance, capture threshold, and sense amplitude deviations would have been an obvious matter of engineering design choice because Applicant has not disclosed that detecting such ambiguity provides an advantage, is used for a particular purpose, or solves a stated problem. This contention is erroneous.

Applicant's specification discloses that:

It is contemplated that an ambiguity in the impedance, capture threshold, and sense amplitude deviations may be detected. In one approach, atrial ATP therapy delivery is disabled in response to the detected ambiguity. According to another approach in which such an ambiguity is detected, atrial ATP therapy delivery is disabled in response to the measured impedance deviating from the impedance limit by a predetermined factor. In a further approach, atrial ATP therapy delivery is disabled in response to the measured impedance deviating from the impedance limit by the predetermined factor irrespective of the presence or lack of ambiguity relative to the capture threshold and sense amplitude deviations. In these last two approaches, atrial lead impedance is considered the more reliable indicator for detecting atrial lead dislodgment. [page 16, line 25 through page 17, line 5]

The control system 100 may further detect an ambiguity in the impedance, capture threshold, and sense amplitude deviations, and disable atrial ATP therapy delivery in manners previously described above in response to detecting such an ambiguity. [page 20, lines 22-25]

Respectfully, these and other portions of Applicant's specification clearly disclose one or more of an advantage, use for a particular purpose, or a solution to a stated problem which is achieved by detecting an ambiguity in the impedance, capture threshold, and sense amplitude deviations.

Obviousness under § 103 requires an objective analysis of the following: “the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art are resolved.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007) (quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966)). Evidence of secondary considerations must also be considered. *Id.*

Applicant respectfully submits that the Office Action is defective in that the scope and content of the prior art has not been accurately determined by the Examiner. Errors in the Examiner’s characterization of the asserted references presented in the Office Action are described above. The defective characterization of the prior art teachings in the Office Action renders the differences between the prior art and the claims at issue unascertained. For at least these reasons, the Examiner’s conclusion of obviousness is erroneous and unsustainable.

The combination of Ritscher and Levine clearly does not teach or suggest all features of Applicant’s independent claims 1, 20, and 36. The asserted combination does not render independent claims 1, 20, and 36 obvious. The claims that depend from independent claims 1, 20, and 36 are also not rendered obvious by the combination of Ritscher and Levine. It is well settled that, if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. MPEP § 2143.03; *citing In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

To the extent that the current response does not respond to any characterization in the Office Action of the asserted art or of the claimed subject matter, or to any application in the Office Action of the asserted art to any claimed subject matter, it is stated for the record that any such lack of response should not be interpreted as an acquiescence to such characterizations or applications. A detailed discussion of each of the Office Action’s characterizations, or any other assertions or statements beyond that provided above is unnecessary in view of the present response. The right to address in detail any such assertions or statements in the future is reserved. It is respectfully submitted that the application is in condition for allowance, timely notification of which is kindly requested.

Applicant submits that all claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Authorization is given to charge Deposit Account No. 50-3581 (GUID.014US01) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,
HOLLINGSWORTH & FUNK, LLC
8500 Normandale Lake Blvd., Suite 320
Minneapolis, MN 55437
952.854.2700

Date: June 23, 2011

By: /Erin Nichols Matkaiti/
Erin Nichols Matkaiti
Reg. No. 57,125

By: /Mark A. Hollingsworth/
Mark A. Hollingsworth
Reg. No. 38,491